K062821

5. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEC 19 2006

Establishment Registration Number: 2021898

Address of Manufacturer: Medtronic Neurosurgery
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 Phone
(805) 968-9336 Facsimile

Contact Person: Jeffrey Henderson

Date: September 19, 2006

Trade or Proprietary Name: U-CLIP™ Device

Common usual or Classification Name: Clip, Implantable 21CFR878.4300 (FZP)

Description: The U-CLIP™ Device is a self-closing clip for dura mater and prosthetic material approximation or attachment applications. The U-CLIP™ consists of a self-closing Nitinol clip connected to surgical needles via flexible members. The U-CLIP™ includes a Nitinol wire coil surrounding the Nitinol wire core. This design allows precise placement of clips prior to closure and facilitates an interrupted "suture" technique by eliminating knot tying. The device is manufactured from a standard implantable grade of Nitinol.

Intended Use: The U-CLIP™ Device is intended for endoscopic and non-endoscopic dura mater and prosthetic material approximation/attachment and/or ligation in neurosurgical procedures.

Contraindications: Do not use for tubal ligation.

Predicate Device Identification: The U-CLIP™ Device is substantially equivalent to the following predicate device:

- U-CLIP™ Device - K062057, K053252, K013664

The predicate devices intended for tissue approximation have been cleared for neurological applications include:

- Ethicon, Polypropylene, PRONOVA Nonasbsorbable Suture - K001625
- Surgilon/Polyamide Nonabsorbable Surgical Suture – K981582

Predicate Device Intended Use: The U-CLIP™ Device is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures.

Comparison to Predicate Device: Medtronic Neurosurgery submits that the device design, fabrication, packaging, specifications, and the fundamental scientific technology of the U-CLIP™ device is identical to the U-CLIP™ (K062057, K053252, and K013664). The specific neurosurgical indication is substantially equivalent to the Ethicon PRONOVA Nonabsorbable Suture (K001625) and the Surgilon/Polyamide Nonabsorbable Surgical Suture (K981582).

Test Data: In vivo testing confirmed that the U-CLIP Device is comparable to the predicate, standard non-absorbable suture, for dura approximation application.

Summary: Based upon the product technical information, intended use, in vitro, in vivo, and clinical performance information provided in this and previous pre-market notifications, the U-CLIP Device has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Neurosurgery
% Mr. Jeffrey Henderson
Vice President, Quality &
Regulatory Affairs
125 Cremona Drive
Goleta, California 93117-5500

DEC 19 2006

Re: K062821
Trade/Device Name: U-CLIP™ Device
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: September 19, 2006
Received: November 8, 2006

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062821

K062821

4. Indications for Use Statement

510(k) Number (if known): K062821

Device Name: U-CLIP™ Device

Indications for Use:

The U-CLIP™ Device is intended for endoscopic and non-endoscopic dura mater and prosthetic material approximation/attachment and/or ligation in neurosurgical procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062821